Amendments to the Claims

Please amend claims 10 and 32 under the provisions of 37 C.F.R. §1.121, as set forth in the Federal Register on June 30, 2003. The following listing of claims will replace all prior versions, and listings, of claims in the application:

1. (Previously Amended) A pharmaceutical composition comprising an aqueous carrier;

from 0.1 mg/ml to 20 mg/ml of the composition of a pharmaceutically acceptable salt of a peptide having the structural formula

NH_2-Gly Tyr Tyr Trp Ser Trp Ile Arg Gln Pro Pro Gly Lys Gly Glu Glu Trp Ile Gly-COOH (SEQ ID NO:1); and

a substituted β-cyclodextrin in an amount effective to dissolve the peptide in the aqueous carrier,

wherein the pharmaceutical composition has a pH between 4 and 9.

2. (Original) The pharmaceutical composition of claim 1, wherein the concentration of the salt of the peptide is at least 0.5 mg/ml.

3. (Original) The pharmaceutical composition of claim 2, wherein the concentration of the salt of the peptide is from 0.5 mg/ml to 10 mg/ml.

4. (Original) The pharmaceutical composition of claim 3, wherein the concentration of the salt of the peptide is from 0.5 mg/ml to 2.5 mg/ml.

5. (Previously Presented) The pharmaceutical composition of claim 1 wherein the composition has a pH between 6.5 and 8.5.

6. (Original) The pharmaceutical composition of claim 5, wherein the composition has a pH between 7.5 and 8.5.

7. (Previously Presented) The pharmaceutical composition claim 1 wherein the pharmaceutically acceptable salt is an acetate salt.

8. (Previously Presented) The pharmaceutical composition of claim 1 wherein the substituted β-cyclodextrin is a hydroxypropyl, a sulfobutyl ether, or a sulfopropyl ether substituted β-cyclodextrin.

9. (Original) The pharmaceutical composition of claim 8, wherein the substituted β-cyclodextrin is a sulfobutyl ether substituted β-cyclodextrin.

10. (Currently Amended) The pharmaceutical composition of claim ~~7~~9, wherein the substituted β-cyclodextrin is hepta-(sulfobutyl ether)-β-cyclodextrin.

11. (Previously Presented) The pharmaceutical composition of claim 1 further comprising a pharmaceutically acceptable buffer in an amount and of a type suitable to make the pH of the pharmaceutical composition in the range of 4-9.

12. (Previously Amended) A pharmaceutical composition comprising

an aqueous carrier;

from 0.1 mg/ml to 20 mg/ml of the composition of an acetate salt of a peptide having the structural formula NH_2-Gly Tyr Tyr Trp Ser Trp Ile Arg Gln Pro Pro Gly Lys Gly Glu Glu Trp Ile Gly-COOH (SEQ ID NO:1); and

from 70 mg/ml to 170 mg/ml of the composition of hepta-(sulfobutyl ether)-β-cyclodextrin,

wherein the peptide and the hepta-(sulfobutyl ether)-β-cyclodextrin are dissolved in the aqueous carrier; and
wherein the pharmaceutical composition has a pH between 6.5 and 8.5.

13. (Original) The pharmaceutical composition of claim 12, wherein the concentration of the acetate salt of the peptide is at least 0.5 mg/ml.

14. (Original) The pharmaceutical composition of claim 13, wherein the concentration of the acetate salt of the peptide is from 0.5 mg/ml to 10 mg/ml.

15. (Original) The pharmaceutical composition of claim 13, wherein the concentration of the acetate salt of the peptide is from 0.5 to 2.5 mg/ml.

16. (Previously Amended) The pharmaceutical composition of claim 13, wherein the concentration of hepta-(sulfobutyl ether)-β-cyclodextrin is 120 mg/ml, and wherein the pH of the pharmaceutical composition is between 7.5 and 8.5.

17. (Original) The pharmaceutical composition of claim 16, wherein the concentration of the acetate salt of the peptide is 1.0 mg/ml.

18. (Original) The pharmaceutical composition of claim 16, wherein the concentration of the acetate salt of the peptide is 2.5 mg/ml.

19. (Original) A method of alleviating symptoms of systemic lupus erythematosus (SLE) in a human subject comprising administering to the human subject the pharmaceutical

composition of claim 1 in an amount effective to alleviate the symptoms of SLE in the human subject.

Claim 20. (Canceled)

21. (Previously Presented) A process for manufacturing the pharmaceutical composition of claim 1 comprising the steps of:

a) preparing a solution of a substituted β-cyclodextrin in an aqueous carrier at a predetermined concentration;
b) adding a predetermined amount of a pharmaceutically acceptable salt of the peptide NH_2-Gly Tyr Tyr Trp Ser Trp Ile Arg Gln Pro Pro Gly Lys Gly Glu Glu Trp Ile Gly-COOH (SEQ ID NO:1) to the solution of step a);
c) adjusting the pH of the solution of step b) until the peptide dissolves in the solution; and
d) if necessary, adjusting the pH of the solution of step c) to a pH of 4-9, thereby manufacturing the pharmaceutical composition.

Claims 22-30. (Canceled)

31. (Previously Presented) A pharmaceutical composition prepared by the process of claim 21.

32. (Currently Amended) A process of lyophilizing the pharmaceutical composition of claim 2, comprising the steps of:

a) lowering the temperature of the pharmaceutical composition to -40°C;
b) holding the temperature at -40°C for a predetermined time;
c) raising the temperature of the solution to 20°C;

d) holding the temperature at 20°C for a predetermined time; and

e) reducing the pressure in step d) to a pressure suitable for lyophilization and holding the temperature at 20°C for a predetermined time, thereby lyophilizing the pharmaceutical composition.

Claims 33-40. (Canceled)

41. (Original) The process of claim 32, wherein
step a) is performed within 2 hours;
step b) is performed within 3 hours;
step c) is performed over 13 hours and at a pressure of 110µbar;
step d) is performed over 13 hours and at a pressure of 110µbar; and
step e) is performed over 5 hours and the pressure is reduced to 10µbar.

42. (Previously Presented) A lyophilized pharmaceutical composition prepared by the process of claim 32.

43. (Previously Presented) A process of lyophilizing the pharmaceutical composition of claim 2, comprising the steps of:

a) lowering the temperature of the pharmaceutical composition to -45°C;

b) holding the temperature at -45°C for a predetermined time;

c) raising the temperature of the solution to -20°C;

d) raising the temperature of the solution to 25°C; and

e) holding the temperature at 25°C for a predetermined time, thereby lyophilizing the pharmaceutical composition.

Claims 44-51. (Canceled)

52. (Original) The process of claim 43, wherein
step a) is performed within 6 hours;
step b) is performed within 3 hours;
step c) is performed over 19 hours and at a pressure of 150μbar;
step d) is performed over 13 hours and at a pressure of 150μbar; and
step e) is performed over 8 hours and at a pressure of 150μbar.

53. (Original) A lyophilized pharmaceutical composition prepared by the process of claim 43.

Claims 54-56. (Canceled)

57. (Original) A lyophilized pharmaceutical composition comprising a pharmaceutically acceptable salt of a peptide having the structural formula
NH_2-Gly Tyr Tyr Trp Ser Trp Ile Arg Gln Pro Pro Gly Lys Gly Glu Glu Trp Ile Gly-COOH (SEQ ID NO:1); and
a substituted β-cyclodextrin.

58. (Previously Amended) A packaged pharmaceutical composition comprised of:
a packaging material; and
the lyophilized pharmaceutical composition of claim 57.

59. (Previously Amended) The lyophilized pharmaceutical composition of claim 53, wherein the water content of the pharmaceutical composition is less than 5%.

60. (Previously Amended) The lyophilized pharmaceutical composition of claim 59, wherein the water content of the pharmaceutical composition is less than 4.0%.

61. (Previously Amended) The lyophilized pharmaceutical composition of claim 60, wherein the water content of the pharmaceutical composition is less then 3.5%.